TRANSMITTAL OF APPEAL BRIEF (Small Entity)

Docket No. 115588-023

In Re Application Of:

Gholman Peyman

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
09/815,277	March 23, 2001	Shay, David	29180	2836	4578

Invention: **ADJUSTABLE ABLATABLE INLAY**

COMMISSIONER FOR PATENTS:

Transmitted herewith the Appeal Brief in this application, with respect to the Notice of Appeal filed on:

June 15, 2004

☒ Applicant claims small entity status. See 37 CFR 1.27

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Dated: October 15, 2004

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellant(s):	Gholam A. Peyman
Appl. No.:	09/815,277
Conf. No.:	4578
Filed:	March 23, 2001
Title:	ADJUSTABLE ABLATABLE INLAY
Art Unit:	2836
Examiner:	Shay, David
Docket No.:	115588-023

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

Appellants submit this Appeal Brief in support of the Notice of Appeal filed on June 15, 2004. This Appeal is taken from the Final Rejection dated December 15, 2003.

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I. Real Party in Interest

The real party in interest in this application is assignee MINU, L.L.C.. This application was assigned to MINU, L.L.C. by the inventor in an assignment recorded at Reel 13886, Frame 0422.

II. Related Appeals and Interferences

There are no other related appeals or interferences known to Appellant, Appellant's legal representative, or Assignee, which would directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. Status of the Claims

Claims 1-15, 17-21, 23, and 31-35 are pending and are on appeal. No claim is allowed.

Claims 9, 10, 12, 13, 21, 23, 26, 27, 33 and 34 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Claims 1-4, 7-13, 17-19, 31, 34 and 35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,907,586 to Bille et al. in combination with U.S. Patent No. 3,776,230 to Neefe and U.S. Patent No. 5,090,955 to Simon. Claims 1, 4-6, 14, 15, and 31-33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Bille et al. patent in combination with the Neefe patent, U.S. Patent No. 4,665,913 to L'Esperance, Jr. and the Simon patent. Claims 20, 21, and 23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Bille et al. patent in combination with the L'Esperance, Jr. patent and the Simon patent.

IV. Status of the Amendments

The Applicant filed an Amendment under 37 C.F.R. § 1.116 on April 30, 2004. In an Advisory Action mailed on June 3, 2004, the Examiner indicated that the amendments would be entered upon appeal.

V. Summary of the Claimed Subject Matter

Although specification citations are given in accordance with C.F.R. 1.192(c), these reference numerals and citations are merely examples of where support may be found in the specification for the terms used in this section of the brief. There is no intention to suggest in anyway that the terms of the claims are limited to the examples in the specification. Although as demonstrated by the references numerals and citations below, the claims are fully supported by the specification as required by law, it is improper under the law to read limitations from the specification into the claims. Pointing out specification support for the claim terminology as is done here to comply with rule 1.192(c) does not in any way limit the scope of the claims to those examples from which they find support. Nor does this exercise provide a mechanism for circumventing the law precluding reading limitations into the claims from the specification. In short, the references numerals and specification citations are not to be construed as claim limitations or in any way used to limit the scope of the claims.

To focus, the cornea and lens of an eye must bend or refract light entering the eye onto the retina; however, many eyes have refractive error—i.e. they do not refract light onto the retina properly. Common refractive errors include myopia (near-sightedness), hyperopia

(farsightedness) and astigmatism. In each of these conditions, the cornea and/or the lens focuses the light on a location in eye other than the retina, causing blurred vision. The present invention relates to a method of correcting these types of refractive error. In particular, the present invention relates to a method of correcting refractive errors by reshaping the cornea of the eye using a laser and implanted ocular material.

Independent Claim 1

With reference to Fig. 1, the cornea 20 is modified by aiming a laser 12 at the internal portion of the cornea 20 and firing the laser 12 at the cornea 20. *See* ¶ [0051]. This separates the internal layers of the cornea 20 forming a first internal surface and a second internal surface, which form an internal pocket 18. *See* ¶ [0051] As shown in Figures 2-5, an opening 38 is formed between the external surface 28 of the cornea 16 and the internal pocket 18. *See* ¶ [0053]. Additionally, Fig. 6 shows ocular material 22 being introduced into the internal pocket 18 through the opening 38. *See* ¶ [0046 and 0054]. Further, as shown in Figs. 7 and 8 a contact lens 29 having a predetermined curvature is placed on the external surface of the cornea to shape the ocular material. *See* ¶ [0055].

Independent Claim 20

As shown in Fig. 1, the cornea 20 is modified by aiming and firing an ultrashort pulse laser 12 at the cornea 20. *See* ¶¶ [0051 and 0052]. The laser 12 separates the internal area of the cornea offset from the main optical axis 32 of the cornea 20 in to first and second substantially ring-shaped internal surfaces 14 and 16 to form a corneal pocket 18. *See* ¶ [0051]. A portion 34 of the first internal surface 14 remains attached to the second internal surface 16 by an area located at the main optical axis 32. *See* ¶ [0051]. The first surface 14 faces in a posterior

direction of the cornea 20 and the second surface 16 faces in an anterior direction of the cornea. *See* ¶ [0051]. As shown in Figs. 2-5, an opening 38 is formed from the external surface 28 of the cornea 20 to the pocket 18. *See* ¶ [0053]. As shown in Fig. 8, ocular material 22 is introduced through the opening 38 and into the internal pocket 18, so that the ocular material 22 at least partially encircles the portion 34 of the first surface 14 that remains attached to the second surface 16 by the area at the main optical axis 34. *See* ¶¶ [0046 and 0054]. As shown in Fig. 23, a second laser 44 is aimed and fired at the external surface 28 of the cornea 20 to ablate a portion 26 of the external surface 28 of the cornea 20 overlying the portion 34 of the first surface 14 that remains attached to the second surface 16. *See* ¶ [0064].

Independent Claim 31

With reference to Fig. 1, the cornea 20 is modified by aiming an ultrashort laser 12 at the internal portion of the cornea 20 and firing the laser 12 at the cornea 20. *See* ¶ [0051 and 0052]. The first surface 14 faces in a posterior direction of the cornea 20 and the second surface 16 faces in an anterior direction of the cornea. *See* ¶ [0051]. This separates the internal layers of the cornea 20 forming a first internal surface and a second internal surface, which form an internal pocket 18. As shown in Fig. 2-5, an opening 38 is formed from the external surface 28 of the cornea 20 to the pocket 18. *See* ¶ [0053]. As shown in Fig. 6, ocular gel 22 is introduced through the opening 38 and into the internal pocket 18. *See* ¶ [0046]. As shown in Figs. 21 and 22, the ocular gel 22 is irradiated so that it solidifies. *See* ¶¶ [0057]-[0059].

VI. Grounds of Rejection to be Reviewed on Appeal

The following issues are presented for review.

1. Claims 9, 10, 12, 13, 21, 23, 26, 27, 33, 34 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

2. Claims 1-4, 7-13, 17-19, 31, 34, and 35 stand rejected under 35 U.S.C. § 103(a) as being obvious over the Bille, Neefe, and Simon patents.

3. Claims 1, 4-6, 14, 15, and 31-33 stand rejected under 35 U.S.C. § 103(a) as being obvious over the Bille, Neefe, L'Esperance, and Simon patents.

4. Claims 20, 21, and 23 stand rejected under 35 U.S.C. § 103(a) as being obvious over the Bille, L'Esperance, Jr. and Simon patents.

VII. Argument

A. The Rejection of Claims 9, 10, 12, 13, 21, 23, 26, 27, 33, and 34 Under 35 U.S.C. § 112, Second Paragraph, Should Be Reversed Because The Claims Apprise One Skilled In The Art Of The Bounds Of The Claim.

Claims 9, 10, 12, 13, 21, 23, 26, 27, 33 and 34 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Examiner states that these claims "merely recite the use of particular structure, thus what further manipulative aspect of the method is intended to be specified is unclear". *See* Final Office Action, December 15, 2003, p. 2.

This rejection should be reversed because the claims apprise those skilled in the art of the scope of the invention. The standard for assessing whether a claim is sufficiently definite is simply stated: If one skilled in the art would understand the bounds of the claim when read in light of the specification, then the claim satisfies section 112, paragraph 2. *See S3 Inc. v. nVidia Corp.*, 259 F.3d 1364, 1367, 59 U.S.P.Q.2d 1745, 1747 (Fed. Cir. 2001). There is no requirement that a method claim recite a "further manipulative aspect".

(1) Dependent Claims 9 and 10

The bounds of each of the rejected claims can easily be understood by one skilled in the art. Addressing claims 9 and 10 first, both of these claims are dependent claims that ultimately depend from claim 1. Claim 1 is a method claim, and includes the step of "introducing ocular material through [an] opening and into [an] internal pocket of the cornea." Both claims 9 and 10 relate to the particular type of ocular material that is introduced during this step. Claim 9 specifies that "the introducing ocular material step includes introducing a lens." Claim 10 specifies that the implanted "lens is substantially ring-shaped." These limitations are illustrated in FIGS. 9-10 and described in the specification, which explains:

> The ocular material 22 can be a lens. When a lens, it can be any shape or sized [sic] desired. As seen in Figs. 6-15, the lens is preferably substantially ring-shaped; but can be a circular or semi-circular inlay.

See ¶ [0050].

In view of the figures and specification, the limitations of claims 9 and 10 are clear. Claim 1 broadly claims a method which includes the step of introducing any type of ocular material. Claim 9 more specifically claims a method that includes the step of introducing a lens. Claim 10 even more specifically claims a method that includes the step of introducing a substantially ring-shaped lens. One skilled in the art easily understands the bounds of claims 9 and 10.

(2) Dependent claims 12, 13, 21, 23, 33 and 34

With respect to claims 12, 13, 21, 23, 33, and 34, each of these claims is a dependent claim and relates to the use of a particular type of laser to perform the refractive error correction

disclosed and claimed in this application. For example, claim 12 depends from claim 1. Claim 1 recites, among other things, "aiming a first laser at the internal portion of the cornea" and "firing the first laser at the cornea." Claim 12 specifies that "the steps of aiming and firing a first laser include aiming and firing an ultrashort pulse laser." The specification discusses the use of an ultrashort pulse laser at ¶ [0052]. In view of this discussion, claim 12 is easily understood—it requires aiming and firing an ultrashort pulse laser. One skilled in the art has no difficulty understanding the bounds of claim 12. The limitations in claims 13, 21, 23, 33, and 34 also relate to details of the laser used in the present invention. Like claim 12, these claims are readily understood, and one skilled in the art has no trouble understanding the bounds of these claims.

Each of the rejected claims apprises one of ordinary skill in the art of the scope of the claim. They therefore meet the requirements of 35 U.S.C. § 112, second paragraph, and the Examiner's rejection of claims 9, 10, 12, 13, 33, and 34 for indefiniteness should be reversed.

B. <u>The Board Should Reverse The Rejection of Claims 1-4, 7-13, 17-19, 31, 34, and 35 Under 35 U.S.C. § 103(a) over the Bille Patent in combination with the Neefe Patent and the Simon Patent Because The Examiner Has Not Established A *Prima Facie* Case Of Obviousness</u>

The Examiner has rejected claims 1-4, 7-13, 17-19, 31, 34, and 35 under 35 U.S.C. § 103(a) over U.S. Patent No. 4,907,586 ("the Bille patent") in combination with U.S. Patent No. 3,776,230 ("the Neefe patent") and U.S. Patent No. 5,090,955 ("the Simon patent"). The rejection of these claims should be reversed because the Examiner has not established a *prima facie* case of obviousness for two reasons. First, the rejection fails because the Examiner has not established a motivation to combine the three references which is supported by actual evidence.

Second, even if the three references are combined, the combined references do not disclose or suggest all of the limitations of the claims.

1. The Examiner Has Failed To Establish A Motivation To Combine Which Is Supported By Actual Evidence.

To establish a *prima facie* case of obviousness, the Examiner must show that "some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead [an]individual to combine the relevant teachings of the references." *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). "The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved." *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). The showing must be "clear and particular, and it must be supported by actual evidence." *Teleflex, Inc. v. Ficosa North Ametican Corp.*, 299 F.3d 1313, 1334, 63 U.S.P.Q.2d 1374, 1387 (Fed. Cir. 2002) (quoting *In re Dembiczak*, 175 F.3d 994, 999, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999)). It is not sufficient to rely on "common sense and common knowledge," there must be specific evidence to support the motivation. *See In re Lee*, 277 F.3d. 1338, 1344-45, 61 U.S.P.Q.2d 1430, 1434-35 (Fed. Cir. 2002).

In the rejection of these claims, including independent claims 1 and 31, the Examiner has made no showing of motivation to combine based on actual, specific, evidence. With respect to the combination of the Bille et al. patent with the Simon patent, the Examiner cites the Bille et al. patent as disclosing a method of forming a pocket in the stroma using an ultrashort pulse laser

and the Simon patent as teaching a method of forming an intrastromal pocket and inserting a gel therein. The Examiner asserts that it "would have been obvious to the artisan of ordinary skill to employ the laser of Bille et al. in the method of Simon, since this could form the intrastromal pocket much more precisely that the mechanical device of Simon and will not accidentally perforate the lamellae." *See* Final Office Action, 12/15/03, page 2.

The Examiner cites no evidence in support of this purported motivation. None of the references relied upon by the Examiner suggest that the laser of the Bille patent is more precise than the mechanical device of the Simon patent. Nor do any of the references suggest that the mechanical device of Simon will accidentally perforate the lamellae while the laser of the Bille patent will not. These assertions are unsupported by any actual, specific, evidence.

With respect to the proposed combination with the Neefe patent, the Examiner cites the Neefe patent as teaching a method of adjusting corneal curvature using a mold. The Examiner asserts that "it would have been obvious to the artisan of ordinary skill . . . to employ a mold [as taught in the Neefe patent] in the method of Bille et al ('586) or Simon since this would be more precise and less cumbersome than the manual massage method of Simon for removing excess gel. . . ." *See* Final Office Action, 12/15/03, page 2. The teachings of the Neefe patent, however, are unrelated to the methods of the Bille patent and the Simon patent.

Both the Bille patent and the Simon patent relate to methods for changing the shape of the cornea of an eye by modifying the *internal* structure of the cornea. The Neefe patent, on the other hand, relates to a method of modifying the *exterior* shape of a cornea. It teaches two methods of changing the exterior shape of the cornea. The first is to apply a heated metal mold to the eye. *See* Neefe patent, col. 1, lines 36-44. The heat softens the corneal tissues and allows

for the mold to shape the exterior, corneal surface. The second method uses chemical agents on the corneal mold to soften the corneal tissues. *See id.* at col. 1, lines 22-26. The Neefe patent's preferred embodiment uses a combination of the heat and chemical methods to reshape the exterior of the cornea. *See id.* at col. 1, lines 64-65.

The Examiner suggests that the methods of the Neefe patent, which relate to reshaping the exterior surface of the cornea with heat and chemicals, would be useful for reshaping an implanted gel within the cornea—i.e. that the Neefe patent "would be more precise and less cumbersome than the manual massage method of Simon for removing excess gel." *See* Final Office Action, 12/15/03, page 2. Nowhere does the Neefe patent suggest that it would be useful for removing excess gel from a gel implant within a pocket in the cornea. The idea that one of ordinary skill in the art would use the metal mold of the Neefe patent to reshape a gel implant is totally devoid of any support in any of the references.

In this rejection, the Examiner has cited several prior art references that teach a few elements of the Applicant's claimed invention, and created motivation to combine them; however, none of the cited references actually teach or suggest the Examiner's proposed motivation. This is impermissible. A motivation to combine must be clear and particular, and be supported by actual, specific evidence. *See Teleflex*, 299 F.3d at 1334, 63 U.S.P.Q.2d at 1387; *Lee*, 277 F.3d at 1344-45, 61 U.S.P.Q.2d at 1434-35. Because the Examiner has not identified a motivation to combine which is supported by actual, specific evidence, the Examiner has failed to establish a *prima facie* case of obviousness. Accordingly, the Board should reverse the rejection of claims 1-4, 7-13, 17-19, 31, 34, and 35 under 35 U.S.C. § 103(a) over the Bille patent in combination with the Neefe patent and the Simon Patent.

2. The Proposed Combination Of Prior Art References Does Not Disclose or Suggest All of the Limitations Of The Claims

Even if one were to combine the three references as suggested by the Examiner, the rejection of the claims is still improper because the proposed combination of references does not disclose all of the limitations of all of the claims. To establish a *prima facie* case of obviousness, the prior art must disclose or suggest all of the limitations of the claims. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974).

(a) Independent Claim 1

With respect to claim 1 and its dependent claims, these claims all require the step of "introducing ocular material . . . into the internal pocket of the cornea" and "placing a contact lens having a predetermined curvature on the external surface of the cornea to shape the ocular material." The Examiner does not precisely identify what meets the contact lens limitation, but apparently is relying on the metal concave mold of the Neefe patent to meet the limitation. First, it is clear that the metal concave mold of the Neefe patent is not a contact lens. A lens, as defined in the specification at ¶ [0055], is transparent to visible light, and a metal mold is clearly not transparent. Second, the Neefe patent, as previously discussed, relates to reshaping the exterior corneal surface of the eye with a metal concave mold. Even if one were to combine the Neefe patent with the Bille patent and the Simon patent, it would merely teach reshaping the exterior corneal surface of the eye with a metal concave mold. It would not disclose or suggest the recited limitation of "placing a contact lens having a predetermined curvature on the external surface of the cornea to shape the ocular material" which is located in an internal pocket in the

cornea. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness with respect to claim 1 and its dependent claims, and the rejection of these claims should be reversed for this reason.

(i) Dependent Claims 2 and 3

Claims 2 and 3 recite the step of "irradiating the ocular material so that a portion of the ocular material expands" or "irradiating the ocular material so that a portion of the ocular material contracts." The Examiner does not cite any prior art disclosing or suggesting this limitation. Instead, the Examiner merely states that "it would have been obvious to the artisan of ordinary skill to . . . irradiate the gel to expand or contract the gel, since this would enable adjustment of astigmatism." *See* Final Office Action, 12/15/03, page 2. Although the Examiner's statement that this would enable adjustment of astigmatism is true, there is no support in the cited references for this motivation. The only support for the statement is in the Applicant's own specification. None of the references disclose or suggest irradiating an implanted material to expand or contract the material. The Examiner has therefore failed to establish a *prima facie* case of obviousness with respect to claims 2 and 3, and the rejection of these claims should be reversed for this reason.

(ii) Dependent Claims 9 and 10

Similarly, the proposed combination of the Bille patent, the Simon patent, and the Neefe patent does not disclose or suggest all of the limitations of claims 9 and 10. Claim 9, which depends from claim 1, specifies that "the introducing ocular material step includes introducing a lens." None of the Bille, Neefe, or Simon patents discloses or suggests implanting a lens in the

eye. Thus, the rejection of claim 9, and claim 10 that depends from claim 9, should be reversed for this reason.

(iii) Dependent Claim 19

Claim 19 specifies the steps of "applying a chemical to the external surface of the cornea, and passing the chemical from the external surface of the cornea to the internal pocket to polymerize the ocular material." This is described in the specification at paragraph [0060], where the Applicant explains that a chemical can by used to solidify the ocular material implanted into an internal pocket.

None of the references disclose these steps. In support of the rejection, the Examiner makes the assertion that it "would have been obvious to the artisan of ordinary skill to . . . set the gel chemically since this is equivalent to cross linking by irradiation and provides no unexpected results." *See* Final Office Action, 12/15/03, p. 2. Setting a gel chemically is different than cross linking a gel by irradiation, and the Examiner provides no support for the assertion that these different processes are equivalent. But more importantly, none of the cited reference discloses cross linking a gel in an internal pocket by irradiation. The only mention of cross linking by irradiation in any of the references is at col. 6, lines 18-19 of the Simon patent. That reference to cross linking has nothing to do with cross linking an implanted gel in an internal pocket. Rather, it relates to sealing an incision site—i.e. "the corneal incision can be instantly closed-shut by applying a very small amount of collagen gel to the upper lips of the wound and cross linking it with ultraviolet radiation. Such sealing of the incision eliminates post operative patching of the eye . . . ." Simon patent, col. 6, lines 18-19. Sealing an incision site is not equivalent with

irradiating gel in an internal pocket. None of the cited references disclose or suggest the limitations in claim 19, and consequently, the rejection of claim 19 should be reversed.

(b) Independent Claim 31

Claim 31 recites steps of "introducing an ocular gel . . . into the internal pocket" and "placing a contact lens having a predetermined curvature on the surface of the cornea to shape the ocular gel." For the reasons discussed above with respect to claim 1, these limitations are not disclosed or suggested by the proposed combination of references. Furthermore, claim 31 recites "irradiating the ocular gel so that the ocular gel solidifies." As discussed with respect to claim 19, the proposed combination of references fails to disclose this limitation. For these reasons, the rejection of claim 31 and its dependent claims should be reversed.

C. The Board Should Reverse The Rejection of Claims 1, 4-6, 14, 15, and 31-33 Under 35 U.S.C. § 103(a) over the Bille Patent in combination with the Neefe Patent, the L'Esperance, Jr. Patent, and the Simon Patent Because The Examiner Has Not Made A *Prima Facie* Case Of Obviousness

The Examiner has rejected claims 1, 4-6, 14, 15, and 31-33 under 35 U.S.C. § 103(a) over the Bille patent in combination with the Neefe patent, U.S. Patent No. 4,665,913 ("the L'Esperance, Jr. patent") and the Simon patent. This rejection should be reversed because the Examiner has not established a *prima facie* case of obviousness.

First, the addition of the L'Esperance, Jr. patent to the Bille, Neefe, and Simon patents does not cure the fatal defect of not establishing a motivation to combine based on actual evidence, as discussed above. In support of the combination of the four patents, the Examiner has offered the identical motivation previously discussed -- i.e. "It would have been obvious to the artisan of ordinary skill to employ the laser of Bille et al. in the method of Simon, since this

could form the intrastromal pocket much more precisely than the mechanical device of Simon . . ." *See* Final Office Action, 12/15/03, page 3. As discussed, this purported motivation is totally devoid of support based on actual evidence. Accordingly, the rejection of claims 1, 4-6, 15, and 31-33 should be reversed for this reason.

Second, even if one were to combine the four patents, they do still not disclose all of the limitations of the independent claims. Both independent claims 1 and 31, which were rejected over the combination of four patents, recite limitations related to placing a contact lens on the surface of the cornea. As discussed above, the combination of the Bille, Simon, and Neefe patents fail to disclose or suggest these limitations. The L'Esperance, Jr. patent likewise fails to disclose or suggest this limitation. According to the Examiner, the L'Esperance, Jr. patent teaches ablating the corneal surface with an excimer laser to provide optical correction. *See* Final Office Action, 12/15/03, page 3. The addition of the L'Esperance patent fails to cure the above-discussed deficiencies; namely, "introducing ocular material . . . into the internal pocket of the cornea" and "placing a contact lens having a predetermined curvature on the external surface of the cornea to shape the ocular material." Therefore, the rejection of claims 1 and 31, and their dependent claims, should be reversed.

Further, with respect to claim 31, it recites "irradiating the ocular gel so that the ocular gel solidifies." None of the four patents disclose or suggest this limitation. Accordingly, the rejection of claim 31 and its dependent claims is deficient, and should be reversed.

D. <u>The Board Should Reverse The Rejection of Claims 20, 21, and 23 Under 35 U.S.C. § 103(a) over the Bille Patent in combination with the L'Esperance</u>

Patent and the Simon Patent Because The Examiner Has Not Made A *Prima Facie* Case Of Obviousness

The Examiner has rejected claims 20, 21, and 23 under 35 U.S.C. § 103(a) over the Bille patent in combination with the L'Esperance, Jr. patent and the Simon patent. The Board should reverse this rejection because the Examiner has not established a *prima facie* case of obviousness with respect to these claims.

In particular, the Examiner again offers the unsupported motivation to combine as previously discussed—i.e. "It would have been obvious to the artisan of ordinary skill to employ the laser of Bille et al. in the method of Simon, since this could form the intrastromal pocket much more precisely than the mechanical device of Simon . . ." *See* Final Office Action, 12/15/03, page 4. As discussed, this purported motivation is not based on actual, specific evidence. Accordingly, the Examiner has not established a *prima facie* case of obviousness with respect to claims 20, 21, and 23, and the Board should reverse the rejection of these claims.

VIII. Conclusion

For the reasons discussed above, the Board should reverse the rejections of claims 1-15, 17-21, 23 and 31-35.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY _____

Jeffrey J. Howell
Reg. No. 46,402
P.O. Box 1135
Chicago, Illinois 60690-1135
Phone: (202) 955-6832

Dated: October 15, 2004

IX. APPENDIX A- COPY OF CLAIMS ON APPEAL

1. A method of modifying a cornea of an eye, the cornea having an external surface, an internal portion and a main optical axis, the method comprising the steps of

aiming a first laser at the internal portion of the cornea, adjacent the external surface,

firing the first laser at the cornea, which separates the internal portion of the cornea forming a first internal surface and a second internal surface, the first internal surface facing in a posterior direction of the cornea and the second internal surface facing in an anterior direction of the cornea, the first and second internal surfaces forming an internal pocket there between,

forming an opening from the external surface of the cornea to the internal pocket,

introducing ocular material through the opening and into the internal pocket of the cornea; and

placing a contact lens having a predetermined curvature on the external surface of the cornea to shape the ocular material.

2. A method according to claim 1, and further comprising the step of

irradiating the ocular material so that a portion of the ocular material expands.

3. A method according to claim 1, and further comprising the step of

irradiating the ocular material so that a portion of the ocular material contracts.

4. A method according to claim 1, wherein

separating the internal portion of the cornea includes separating the internal portion of the cornea so that a portion of the first surface remains attached to the second surface by an area located at the main optical axis.

5. A method according to claim 4, and further including the steps of

aiming a second laser at the cornea, and

firing the second laser at the external surface of the cornea to ablate a portion of the external surface of the cornea.

6. A method according to claim 5, wherein

the steps of aiming and firing the second laser at the external surface of the cornea to ablate a portion of the external surface of the cornea include aiming and firing the second laser at the surface overlying the portion of the first internal surface that remains attached to the second internal surface by the area located at the main optical axis.

7. A method according to claim 1, wherein

the introducing step includes introducing the ocular material so that the ocular material at least partially encircles the main optical axis.

8. A method according to claim 1, wherein

the firing step includes firing the first laser at the cornea so that the internal pocket is substantially arcuate.

9. A method according to claim 1, wherein

the introducing ocular material step includes introducing a lens.

10. A method according to claim 9, wherein

the lens is substantially ring-shaped.

11. A method according to claim 1, wherein

the step of aiming the first laser at the internal portion of the cornea includes aiming the first laser between the external surface of the cornea and about one-third of the distance from the external surface of the cornea to an interior chamber of the eye.

12. A method according to claim 1, wherein

the steps of aiming and firing a first laser include aiming and firing an ultrashort pulse laser.

13. A method according to claim 12, wherein

the steps of aiming and firing a first laser include aiming and firing an ultra short pulse laser selected from a group consisting of a femtosecond laser, a picosecond laser and an attosecond laser.

14. A method according to claim 1, and further including the steps of

aiming a second laser at the cornea, and

firing the second laser at the external surface of the cornea to ablate a portion of the external surface of the cornea.

15. A method according to claim 14, wherein

the steps of aiming and firing a second laser at the external surface of the cornea include aiming and firing an excimer laser at the cornea.

16. (Canceled)

17. A method according to claim 1, wherein

the step of introducing ocular material includes introducing a gel through the opening and into the internal pocket of the cornea.

18. A method according to claim 17, wherein

the step of introducing a gel through the opening includes introducing the gel through the opening using a needle.

19. A method according to claim 1, and further comprising the steps of

applying a chemical to the external surface of the cornea, and

passing the chemical from the external surface of the cornea to the internal pocket to polymerize the ocular material.

20. A method of modifying a cornea of an eye having a main optical axis and an external surface, comprising the steps of

aiming an ultrashort pulse laser at the cornea,

firing the ultrashort pulse laser at the cornea, the laser separating the internal area of the cornea offset from the main optical axis into first and second substantially ring-shaped internal surfaces to form a corneal pocket, a portion of the first internal surface remaining attached to the second internal surface by an area located at the main optical axis, the first internal surface facing in a posterior direction of the cornea and the second internal surface facing in an anterior direction of the cornea,

forming an opening from the external surface of the cornea to the internal pocket, and

introducing an ocular material through the opening and into the internal pocket of the cornea, so that the ocular material at least partially encircles the portion of the first surface that remains attached to the second surface by the area located at the main optical axis,

aiming a second laser at the cornea, and

firing the second laser at an external surface of the cornea to ablate a portion of the external surface of the cornea overlying the portion of the first surface that remains attached to the second surface by the area located at the main optical axis.

21. A method according to claim 20, wherein

the step of aiming and firing an ultrashort pulse laser include aiming and firing an ultra short pulse laser selected from the group consisting of a femtosecond laser, a picosecond laser and an attosecond laser.

22. (Canceled)

23. A method according to claim 20, wherein

the steps of aiming and firing a second laser at the cornea include aiming and firing an excimer laser at the external surface of the cornea.

24-30. (Canceled)

31. A method of modifying a cornea having a main optical axis and an external surface, comprising the steps of

aiming and firing an ultrashort pulse laser at the cornea, which separates an internal area of the cornea adjacent the external surface into first and second internal surfaces to form an internal pocket, the first internal surface facing in a posterior direction of the cornea and the second internal surface facing in an anterior direction of the cornea,

forming an opening from the surface of cornea to the internal pocket,

introducing an ocular gel through the opening and into the internal pocket and in between the first and second internal surfaces of the internal pocket,

placing a contact lens having a predetermined curvature on the surface of the cornea to shape the ocular gel, and

irradiating the ocular gel so that the ocular gel solidifies.

32. A method according to claim 31, and further comprising

the step of aiming and firing a second laser at a surface of the cornea to ablate a portion of the surface of the cornea.

33. A method according to claim 32, wherein

the step of aiming and firing a second laser at the cornea include aiming and firing an excimer laser at the surface of the cornea.

34. A method according to claim 31, wherein

the step of aiming and firing an ultrashort pulse laser includes aiming and firing an ultrashort pulse laser selected from the group consisting of a femtosecond laser, a picosecond laser and an attosecond laser

35. A method according to claim 31, wherein

the step of irradiating the ocular material includes irradiating the ocular material so that the at least a portion of ocular material changes volume.